



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/776,923	02/11/2004	Michael J. Campbell	65466US-CIP2(53472)	2359

21874 7590 04/18/2007
EDWARDS ANGELL PALMER & DODGE LLP
P.O. BOX 55874
BOSTON, MA 02205

EXAMINER

SHELL, LAURA C

ART UNIT	PAPER NUMBER
----------	--------------

3767

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/776,923

Applicant(s)

CAMPBELL ET AL.

Examiner

Laura C. Schell

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-15, 17-19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9-15, 17-19 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 February 2007 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9, 10, 14 and consequently dependent claims 11-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what the difference between "forming a gas seal around the surgical instrument within the lumen of the trocar" (lines 9-10 of claim 9) and "sealing the passageway between the surgical instrument and the wall of the lumen in the trocar to block the escape of gas" (lines 2-3 of claim 10) is. Furthermore, claim 14 discloses that a valve is used to seal the passageway, which depends from claim 10. It would appear that claims 9 and 10 are the same step, and therefore it is confusing as to the inclusion of a removable valve. Doesn't the gas surrounding the surgical instrument inherently seal the passageway between the surgical instrument and the wall of the lumen of the trocar? Otherwise, wouldn't the surgical instrument not be sealed by the gas?

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and

Art Unit: 3767

the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 9-11 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantell et al. (US Patent No. 6,905,489) in view of Kerr (US 2006/0079925). Mantell discloses a method of maintaining a pneumoperitoneum in a patient undergoing a surgical procedure (col. 7, lines 34-43 disclose that that the instrument is used to insufflate the peritoneum) comprising the steps of: introducing a trocar through a portion of an abdominal wall of a patient (col. 6, lines 55-56 disclose that the instrument is inserted into the abdomen, and col. 10, lines 59-60 disclose that the instrument used can be substituted with a trocar); introducing a surgical instrument through a lumen of the trocar (Figs. 13-15 surgical instrument 88; also col. 4, lines 40-42 disclose that 88 is inserted into and extends through 78); introducing a pressurized gas from a controlled pressure source into the surgical instrument (col. 5, line 66 through col. 6, line 10 disclose that pressurized gas is introduced through stopcock 54 which then flows through instrument 88 as they are connected together); directing the pressurized gas from the surgical instrument into the patient through a passageway between the surgical instrument and a wall of the lumen in the trocar (col. 6, lines 59-65 disclose that fluid

Art Unit: 3767

flows through annular chamber (76) which is within surgical instrument (88) as shown in Fig. 7, and then the fluid flows out opening 94, and as Fig. 6 shows, opening 94 is within 78 so the fluid would then flow between the wall of the lumen of the trocar (78) and the surgical instrument (88) before it flows out the end of the tip and into the body cavity), the pressurized gas from the surgical instrument forming a gas seal around the surgical instrument within the lumen of the trocar, while simultaneously maintaining an operative pneumoperitoneum in the patient (the gas that exits opening 94 would flow between 88 and the interior wall of 78 to form a gas seal. Furthermore, col. 7, lines 34-43 disclose that the pressure is continuously monitored and the continuous flow of gas is adjusted to maintain the pneumoperitoneum); and monitoring the pneumoperitoneum of the patient to provide feedback for maintaining the operative pneumoperitoneum (col. 7, lines 34-43 disclose monitoring the pressure and using the feedback to control the continuous flow of gas to maintain the pneumoperitoneum. Furthermore, col. 8, lines 6-65 disclose that while either of chambers 74 and 76 can be used for insufflation, the other can be used for monitoring pressure, and they can be reversed as well). In further support of the fact that the gas from the surgical instrument forms a gas seal around the surgical instrument within the lumen of the trocar while simultaneously maintaining the pneumoperitoneum, Kerr discloses an insufflating trocar in which surgical instruments are inserted and the insufflation gas is directed through the trocar and around the instruments. Kerr further discloses that the carbon dioxide gas used to insufflate the cavity is also used to seal around the surgical instruments within the trocar (paragraph

[0074] which therefore makes it obvious that the gas used within Mantel's device would also seal around the surgical instrument.

In reference to claim 10, Mantell discloses the step of sealing the passageway between the surgical instrument and the wall of the lumen in the trocar to block the escape of gas introduced into the patient (col. 8, lines 1-5).

In reference to claim 11, Mantell discloses that the step of directing pressurized gas from the surgical instrument into the patient through a passageway between the surgical instrument and a wall of the lumen in the trocar involves directing a flow of pressurized gas through at least one port in a wall portion of the surgical instrument (Fig. 6, port 94).

In reference to claim 14, Mantell discloses that the step of sealing the passageway between the surgical instrument and the wall of the lumen in the trocar includes the step of arranging a removable valve at a proximal end portion of the trocar (col. 8; lines 1-5).

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantell et al. (US Patent No. 6,905,489) in view of Kerr (US 2006/0079925) and further in view of Garrison et al. (US Patent No. 6,309,382). Mantell in view of Kerr discloses the device substantially as claimed except for introducing first and second cannula within the patient in addition to the trocar. Garrison, however, discloses introducing a trocar (Fig. 1, element 2) as well as introducing a first cannula (10) with a surgical instrument introduced into the first cannula, as well as introducing a second

Art Unit: 3767

cannula (6) and the step of monitoring the pneumoperitoneum of the patient occurs through the second cannula (see boxes in upper right hand corner of Fig. 1 which connect to 6). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantell in view of Kerr with the first and second cannula, as taught by Garrison, in order to provide a surgical system which allows for insufflation as well as other access points within the cavity for other procedures to occur as well.

Claims 15, 17-19 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantell et al. (US Patent No. 6,905,489) in view of Garrison et al. (US Patent No. 6,309,382). Mantell discloses the method substantially as claimed including a method of maintaining an operative pneumoperitoneum in a patient undergoing a surgical procedure (col. 7, lines 34-43 disclose that the instrument is used to insufflate the peritoneum) comprising the steps of: introducing a trocar through a portion of an abdominal wall of a patient (col. 6, lines 55-56 disclose that the instrument is inserted into the abdomen, and col. 10, lines 59-60 disclose that the instrument used can be substituted with a trocar); introducing at least one surgical instrument through a lumen of the trocar (Figs. 13-15 surgical instrument 88; also col. 4, lines 40-42 disclose that 88 is inserted into and extends through 78); introducing a pressurized gas from a controlled pressure source into the at least one surgical instrument (col. 5, line 66 through col. 6, line 10 disclose that pressurized gas is introduced through stopcock 54 which then flows through instrument 88 as they are

Art Unit: 3767

connected together); directing the pressurized gas from the at least one surgical instrument into the patient through a gas passageway between the at least one surgical instrument within the lumen in the trocar (col. 6, lines 59-65 disclose that fluid flows through annular chamber (76) which is within surgical instrument (88) as shown in Fig. 7, and then the fluid flows out opening 94, and as Fig. 6 shows, opening 94 is within 78 so the fluid would then flow between the wall of the lumen of the trocar (78) and the surgical instrument (88) before it flows out the end of the tip and into the body cavity), the pressurized gas forming a gas seal around the at least one surgical instrument within the lumen of the trocar, while simultaneously maintaining the operative pneumoperitoneum (the gas that exits opening 94 would flow between 88 and the interior wall of 78 to form a gas seal. Furthermore, col. 7, lines 34-43 disclose that the pressure is continuously monitored and the continuous flow of gas is adjusted to maintain the pneumoperitoneum).

Mantell, however, does not disclose introducing a cannula in the patient and monitoring and controlling the insufflation through the cannula in the patient. Garrison, however, discloses inserting a cannula into the patient (Fig. 1, cannula is element 6). Garrison further discloses monitoring the gas pressure within the patient through the cannula (boxes 2, 24 and 28) as well as controlling the gas pressure within the patient based upon feedback received from the cannula so as to maintain the pneumoperitoneum with the pressurized gas from the surgical instrument (boxes 2, 24 and 28 are in communication with the cannula (6) as well as the insufflating surgical instrument (2) which therefore completes the loop of monitoring and maintaining, as

seen in Fig. 1 and disclosed within the body of the patent). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantell with the extra cannula and monitoring and controlling through feedback with the addition of the cannula, as taught by Garrison, in order to allow the surgical system to perform many different tasks at the same time.

In reference to claim 17, Mantell discloses the device substantially as claimed except for the trocar and cannula, and both being in communication with one another to balance the gas introduced into the patient. Garrison, however, discloses a cannula (6) in operative communication with the trocar (2, communicating through boxes 24, 28 and 2) to controllably balance the pressurized gas introduced into the patient. Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention to have modified Mantell with the cannula and monitoring system, as taught by Garrison, in order to provide a surgical insufflation system that performs different tasks at the same time without the surgeon having to monitor and adjust the insufflation of the cavity manually, thus allowing the surgical procedure to continue relatively uninterrupted.

In reference to claim 18, Mantell discloses that the trocar has a plurality of surgical instruments extending therethrough simultaneously (Figs. 7 and 9 disclose multiple instruments extending through the trocar 78).

In reference to claim 19, Mantell discloses the method substantially as claimed except for the cannula with an open bore. Garrison, however, discloses that the cannula (Fig. 1, 6) has an open bore which allows operative instruments to pass therethrough (such as instrument 13). Therefore it would have been obvious to one of

Art Unit: 3767

ordinary skill in the art at the time of the invention to have modified Mantell with the cannula with open bore, as taught by Garrison, in order to provide a cannula that allows access for performing other surgical procedures therethrough.

In reference to claim 21, Mantell discloses that the step of directing the pressurized gas from the surgical instrument into the patient involves directing a flow of pressurized gas into the lumen of the trocar at a location distal to any valve arrangement within the trocar (col. 8, lines 1-5 disclose that a valve arrangement would be placed at the proximal end near the stopcocks, and Fig. 6 discloses that the gas exits at port 94 which is distal from the stopcocks).

Response to Arguments

Applicant's arguments with respect to claims 9-15, 17-19 and 21 have been considered but are moot in view of the new ground(s) of rejection.

In reference to Applicant's arguments that Mantel does not disclose a method in which gas is used to form a gas seal around the surgical instrument, as presented above, Mantel discloses that the gas would exit form port 94 and flow between 88 and 78 therefore forming a gas seal around instrument 88. In further support of this flow of air being a gas seal, the examiner brought in the secondary reference of Kerr, which discloses that the insufflation gas that is directed through the trocar is also directed about the instruments within the trocar and thereby also forms a gas seal about the instruments.

In reference to Applicant's arguments that Mantel does not disclose a method of monitoring the pneumoperitoneum to provide feedback for maintaining the pneumoperitoneum, see rejection above.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER



LCS
LCS